



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,649	03/05/2002	Harold T. Hammel	Hammel -001	6107

7590 06/30/2003
Robert J. Yarbrough
Attorney at Law
201 North Jackson St.
Media, PA 19063

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/090,649

Applicant(s)

HAMMEL, HAROLD T.

Examiner

Traviss C McIntosh

Art Unit

1623

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A written description analysis involves three principle factors:

- 1) Field of the invention and predictability of the art,
- 2) Breadth of the claims, and

3) For each claimed species/genus, possession of the claimed invention at the time of the filing.

The breadth of the claims is such that the support in the specification is not adequate for the claims. To provide adequate support for the breadth of the claims, applicant would have to provide sufficient evidence. An adequate representation of species requires that the species which are expressly described are indeed recognized in the art as representative of the entire genus. What constitutes "adequate representation" is an inverse function of the predictability in the art in question (should be supported by the state of the art). The written description requirement for a claimed genus, which in the instant application is "food selected so as to maximize the change in bicarbonate concentration in the pulmonary arterial blood plasma" which comprises any and every compound that would change the bicarbonate concentration (maximize is a relative term which is not defined numerically, see below), may be satisfied through sufficient description of an adequate representation of species by functional characteristics sufficient to show applicant was in possession of the claimed genus.

Applicants should not describe the foods which are to be used in the process by what they do, but by what they are. Describing a substance which is to be used in a methodological process by its properties will not substitute for describing the substance by what it is. Currently, the examiner believes applicants have acceptably shown sucrose and glucose as effective, which is not representative of the entire genus of "foods which will maximize the change in bicarbonate concentrations in the pulmonary arteries blood plasma". This recitation would not allow one of ordinary skill in the art to practice the invention as claimed without undue experimentation, as

Art Unit: 1623

they would be required to determine which foods would maximize the change in bicarbonate concentrations in the pulmonary arteries blood plasma.

As such, a skilled artisan would not recognize the current evidence of record as sufficient evidence. As such, there is not seen any data or correlative prior art evidence which supports applicant's claim that at the time of record they were in possession of the invention as asserted in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "minimize" and "maximize" in all claims are relative terms which render the claims indefinite. The terms "minimize" and "maximize" are not defined by the claim, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Defining the terms with a numerical representation of that which applicant intends as their invention would be seen to obviate the rejection at hand.

Claims 2-9 are confusing. The claims are not written in a way that the examiner can determine exactly that which applicant intends. The claims would read much easier and be more comprehensible if applicants included commas and transition words. For example, claim 3 reads, "the method of claim 2, said digestible carbohydrate further selected so as to minimize a hydrogen content of said food". The claim would be more favorably considered if written as "the

Art Unit: 1623

method of claim 2 wherein said digestible carbohydrate is further selected so as to minimize a hydrogen content of said food”. Likewise, for example, claim 9 reads, “the method of claim 8 said foods containing nitrogen comprising meat and legumes”. It is unclear as to exactly what is intended. This claim would be more favorably read as “the method of claim 8, wherein said foods that contain nitrogen are selected from the group consisting of meat and legumes”. Claims 2, and 4-8 should additionally be corrected in a way to provide clear understanding as to what is being claimed.

Regarding claim 2, the claim does not read in a way which the examiner can determine exactly that which applicant intends. The claim reads, “the method of claim 1, said foods that maximize said change in bicarbonate concentration comprising a digestible carbohydrate selected so as to maximize a carbon content and selected so as to maximize an oxygen content per calorie per gram dry weight of said digestible carbohydrate”. Clarity is required.

Claim 4, which depends from claim 2, is indefinite wherein the claim reads “maximize a ratio of moles of said oxygen to moles of said carbon”. Claim 2 provides the limitation of “maximizing carbon content and maximizing oxygen content”. It is unclear how one can maximize the individual elements contents and maximize the ratio of oxygen to carbon. As set forth supra, defining what is actually intended by a numerical representation would provide a clear understanding to exactly what applicants intend.

Claims 6 and 7 are indefinite wherein the inclusion of parenthetical phrases leaves ambiguity and uncertainty as to whether the contents inside the parenthesis are intended as being that which applicant intends as their invention. For example, claim 6 reads “said digestible carbohydrate comprising glucose ($C_6H_{12}O_6$)”. The parenthetical phrase of $C_6H_{12}O_6$ defines a

Art Unit: 1623

multitude of compounds which are not glucose, specifically all hexoses. Is applicant claiming all hexoses, or glucose? Claim 7 is written in the same manner and is rejected for the same reasons respectively. Clarity is respectfully required.

As currently written, claim 6 recites the limitation "said digestible carbohydrate comprising glucose". There is insufficient antecedent basis for this limitation in the claim as there has been no mention in the claim or the claims from which it depends to a carbohydrate comprising glucose.

Likewise, as currently written, claim 7 recites the limitation "said digestible carbohydrate comprising sucrose". There is insufficient antecedent basis for this limitation in the claim as there has been no mention in the claim or the claims from which it depends to a carbohydrate comprising sucrose. Changing the claims to read "wherein said digestible carbohydrate comprises sucrose" (or glucose in claim 6), would obviate the rejection at hand.

Claim 8 recites the limitation "said foods that contain nitrogen" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim as there has been no mention previously in the claim, or in the claims from which it depends, as to any foods which contain nitrogen.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: to whom the method is to be practiced on. The claims are drawn to "a method of minimizing the incidence and effect of High Altitude Pulmonary Edema comprising...", then lists the steps, but there is no subject or group which is identified as that which the invention is to be practiced on.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

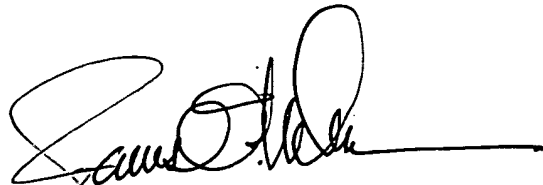
The examiner would like to cite US Patents 6,180,142 B1, 6,174,289 B1, 5,340,603, 5,223,285, 5,116,819, and 4,663,322 as the closest prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'James O. Wilson', with a long horizontal line extending to the right.

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh
June 27, 2003